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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,915	06/27/2003	Stephen L. Hoffman	ABIOS.023A	7068

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

WHALEY, PABLO S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/608,915	Applicant(s) HOFFMAN ET AL.	
	Examiner Pablo Whaley	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/18/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 85-92 and 107-111 is/are pending in the application.
- 4a) Of the above claim(s) 93-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 85-92 and 107-111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

CLAIMS UNDER EXAMINATION

Claims herein under examination are Claims 85-92, 107-111. Claims 1-84 have been cancelled. Claims 93-106 have been withdrawn. Claims 109-111 have been newly added by amendment. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 85-89 and 107-108 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 85 and 107 recite the limitation "combining....wherein the first and second affinities are scaled before they are combined, said scaling comprising a method selected from the group consisting of 1) linear scaling..., 2) nonlinear scaling..., and 3) scaling the affinity...". It is unclear whether "wherein...affinities are scaled" is intended to be an active method step or a limitation of the said first and second affinities. If the applicant's intend for scaling of affinities to be an active method step, the claims should be re-written to reflect this intention. Clarification is requested. Claims 86-89 and 108 are rejected as they depend directly from claims 85 and 107. This rejection is necessitated by amendment.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 85, 87, 88, 89, 90, 92, and 109-111 are rejected under 35 U.S.C. 102 (b) as being anticipated by Rognan et al. (J. Med. Chem., 1999, Vol. 42, p.4650-4658).

Applicant's arguments, filed 05/18/2006, with respect to claims 85-92, 107, and 108 have been considered but are moot in view of the new ground(s) of rejection.

Rognan et al. teach a fast free energy scoring function for predicting the binding free energy of candidate peptides to MHC class I proteins [Abstract]. More specifically, Rognan et al. teach the following aspects of the instantly claimed invention:

- A database of MHC proteins and MHC-bound candidate peptides [Fig. 1], as in instant claims 85, 90, and 109-111.
- Determining binding scores (i.e. affinities) from five different predictive methods, and then combine and evaluate these affinities to determine a single predictive binding affinity [Fig. 1]. As applicant discloses the scoring by individual methods and combining "scores" to determine an overall ranking for peptide binding [Specification, Fig. 2 and 3], the above method taught by Rognan et al. is reasonably interpreted as five distinct

Art Unit: 1631

methods of predictive scoring to determine an overall predictive score. Therefore Rognan et al. anticipates instant claims 85, 90, and 109-111.

- Linear regression analysis (i.e. linear scaling) of the affinity data from each scoring model before they are combined [p.4657, Statistical Analyses], and normalized scaling values between 0 and 1 [Fig. 4], as in instant claims 85, 87, 89, 92, 109-111.
- Predict model applied to nonameric ligands [p.4654, Col. 2, ¶ 2], as in instant claim 88.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 86, 91, 107, and 108 are rejected under 35 U.S.C. 103(a) as being obvious by Rognan et al. (J. Med. Chem., 1999, Vol. 42, p.4650-4658), as applied to claims 85, 87, 88, 89, 90, 92, and 109-111, above, in view of Meister et al. (Vaccine, 1995, Vol. 13, No. 6, p.581-591) and Altuvia et al. (J. Mol. Biol., 1995, 249, 244-250).

Rognan et al. teach a fast free energy scoring function for predicting the binding free energy of candidate peptides to MHC class I proteins [Abstract], as set forth above. Rognan et al. also teach MHC Class I proteins [Abstract], as in instant claim 108.

Rognan et al. do not specifically teach peptides comprising an epitope, as in instant claim 86. However, Rognan et al. suggest the use of this scoring method on a much larger scale for scanning potential MHC binders and epitopes [p.4655, Conclusion].

Meister et al. teach two algorithms based on MHC-binding motifs for predicting T cell epitopes from protein primary structures [Abstract], as in instant claims 86, 91, 107. Meister et al. also teach to use of published epitopes from *mycobacterium tuberculosis* and HIV protein antigens [Abstract].

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to use the *mycobacterium tuberculosis* and HIV protein antigens taught by Meister et al. with the predictive binding method taught by Rognan et al., where the motivation would have been to develop a more accurate predictive tool by incorporating both sequence and interaction energy data [Altuvia, p.246, col.2, lines 1-7] and to improve development of vaccines against these and other pathogens [Meister et al., Abstract], resulting in the practice of the instant claimed invention. One of skill in the art would have had a reasonable expectation of successfully using the protein antigen data of Meister et al. with the predicting binding method of Rognan et al. as both clearly teach predictive binding methods using MHC protein data.

CONCLUSION

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner
Art Unit 1631
Office: 571-272-4425



ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600